

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 6

REMARKS

Claims 26 to 56 are pending. Claims 27, 43 and 44 have been canceled herein, and new claim 57 has been added. Thus, claims 26, 28 to 42 and 45 to 57 are presently under examination.

Applicants appreciate the Examiner's time and helpful comments in the interview on December 18, 2002.

Regarding finality

Applicants appreciate the Examiner's reconsideration of finality and the indication that finality of the present Office Action has been withdrawn. As discussed in the recent interview, claims 42 to 56 had not been amended prior to the present amendment, and therefore, Applicants' amendment cannot have necessitated the new rejection of these claims, as indicated in the Office Action mailed November 18, 2002. Applicants further maintain, for the record, that the scope of the remaining claims (claims 26 to 41) was clear prior to amendment of claim 26; thus, any rejection of claims 26 to 41 could have been made in a first Office Action and was not necessitated by Applicants' amendment.

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 7

Regarding the amendments and new claim

Claims 26, 28 to 42, and 45 to 56 have been amended to more clearly indicate that the recited amino acids of SEQ ID NO:2 are contiguous amino acids. The amendment is supported throughout the specification, for example, at page 10, lines 16-19, which discloses fragments having "contiguous" amino acids of SEQ ID NO:2. Claim 26 also has been amended to indicate that the claimed nucleic acid molecule encodes at least 5 contiguous amino acids of SEQ ID NO:2. The amendment is supported throughout the specification, for example, at page 31, lines 2-4, which indicates that a fragment of an I-2 polypeptide can have, for example, at least 5, 8, 10, 12, 15, 18, 20 or 25 amino acids.

Claim 42 has been amended to indicate that the claimed isolated nucleic acid molecule includes a nucleic acid sequence encoding at least 8 contiguous amino acids of SEQ ID NO:2. The amendment is supported throughout the specification, for example, at page 31, lines 2-4, which indicates that a fragment of an I-2 polypeptide can have, for example, at least 8 amino acids, and at page 6, line 29, to page 7, line 1, which discloses the I-2 amino acid sequence SEQ ID NO:2.

New independent claim 57 is directed to an isolated nucleic acid molecule containing a portion of SEQ ID NO:1 that encodes between six and 100 contiguous amino acids of SEQ ID NO:2. Support for new independent claim 57 can be found in the specification, for example, at page 17,

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 8

lines 2-4, which discloses portions of SEQ ID NO:1 useful, for example, as primers for PCR analysis, and at page 6, line 29, to page 7, line 1, which discloses the I-2 nucleic acid sequence (SEQ ID NO:1) and predicted amino acid sequence (SEQ ID NO:2). Additional support for new claim 57 can be found in the specification, for example, at page 42, lines 3-15, which discloses recombinant nucleic acid molecules encoding peptide fragments of an I-2 polypeptide, and at page 51, lines 23-26, which discloses the I-2 specific primers SEQ ID NOS:3 and 4. Support for the recitation that the isolated nucleic acid molecule encodes between 6 and 100 contiguous amino acids of SEQ ID NO:2 is provided throughout the specification, for example, at page 13, lines 1-15, which discloses amino acid sequences having between 6 and 100 residues of an I-1 polypeptide (SEQ ID NOS:4 and 5) or an I-2 polypeptide (SEQ ID NO:2), and at page 10, lines 16-19, which discloses fragments having "contiguous" amino acids of SEQ ID NO:2.

As set forth above, the amendments and new claim are supported by the specification as filed and do not add new matter. Applicants therefore respectfully request that the Examiner enter the amendments and new claim.

Attached hereto as Appendix A is a marked-up version of the amended claims showing specific text changes made in the enclosed amendments using bracketing to indicate deleted text and underlining to indicate text added.

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 9

Regarding the rejection under 35 U.S.C. § 112, second paragraph

The rejection of claims 26 to 56 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite is respectfully traversed. In rejecting the claims, the Office Action indicates that the newly recited phrase "said portion encoding at least 3 amino acids of SEQ ID NO:2" renders the claims indefinite since there is no limitation requiring that the 3 amino acids are contiguous. The Office Action further asserts that it is not possible to determine which nucleic acid molecules the claim is intended to encompass, for example, in the case of claim 26, the claimed nucleic acid molecule can be from 9 to 301 contiguous nucleotides.

Regarding contiguity of the recited amino acids

Applicants submit that claims 26 to 56 are clear and definite as written and that, in particular, the claims are implicitly directed to nucleic acid molecules encoding contiguous amino acids of SEQ ID NO:2. In this regard, Applicants would point out that, prior to the present amendment, claim 26, for example, recited "a portion" of SEQ ID NO:1 that encodes at least 3 amino acids of SEQ ID NO:2. One skilled in the art understands that a single portion of nucleic acid sequence must necessarily encode a contiguous stretch of the corresponding amino acid sequence. That the claimed nucleic acid molecules encode contiguous amino acids of SEQ ID NO:2 is further supported by the disclosed utilities for the claimed nucleic acid molecules. As taught in the specification at page 16, line 25,

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 10

to page 17, line 4, nucleic acid molecules encoding fragments of SEQ ID NO:2 or portions of SEQ ID NO:1 can be useful, for example, for preparing recombinant polypeptides, or as probes or primers for analysis of I-2 expression. Thus, in view of the claim language and further in view of the specification, Applicants submit that claims 26 to 56 implicitly relate to nucleic acid molecules encoding contiguous amino acids of SEQ ID NO:2.

While maintaining the claims 26 to 56 are clear and definite as written, the claims have been amended herein in order to further prosecution and without prejudice to Applicants pursuing the original subject matter in an application claiming the benefit of priority of the subject application. In view of the above remarks and amendments, Applicants respectfully request the Examiner remove this ground for rejecting claims 26 to 56 under the second paragraph of 35 U.S.C. § 112.

Regarding the length and sequence of the claimed nucleic acid molecules

The Office Action asserts that claims 26 to 56 are indefinite since the claimed nucleic acid molecule may be from 9 to 301 contiguous nucleotides in length. The Office Action further asserts that neither the length nor the sequence of the claimed nucleic acid molecules can be determined and that, therefore, one cannot determine what is claimed due to indefiniteness.

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 11

Applicants submit that the claims are clear and definite as written. Specifically, the claims are not unclear for encompassing nucleic acid molecules having a variety of different lengths or different sequences since one skilled in the art can readily determine if a given isolated nucleic acid molecule falls within the scope of the claims. As an example, in regard to the length and sequence of the isolated nucleic acid molecule of claim 26 as amended, such a molecule includes at least 15 nucleotides of SEQ ID NO:1; such a molecule can further include an additional portion of SEQ ID NO:1 or an additional unrelated nucleic acid sequence, provided that at least 15 contiguous nucleotides of SEQ ID NO:1 are included. Thus, the scope of this claim is clear and unambiguous to the skilled person. Similarly, in regard to the length and sequence of the isolated nucleic acid molecule of amended claim 42, such a nucleic acid molecule has a length of at least 24 nucleotides and has any of several degenerate nucleic acid sequences encoding at least 8 contiguous amino acids of SEQ ID NO:2. Furthermore, in view of the comprising transitional term and the recitation of "at least" 8 contiguous amino acids, it also is clear that the nucleic acid molecule of claim 42 contains, at a minimum, 24 nucleotides but that the nucleic acid molecule also can have a longer length, further including additional sequence related or unrelated to SEQ ID NO:2. Thus, the scope of claim 42, like claim 26, is clear and unambiguous to the skilled person.

As exemplified above for claims 26 and 42, each of claims 26 to 56 have unambiguous boundaries and, thus, the scope of these claims is clear and definite as written. Applicants

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 12

therefore respectfully request that the Examiner reconsider and remove this ground for rejecting the claims under the second paragraph of 35 U.S.C. § 112.

Regarding the rejection of claims 26 to 56 under 35 U.S.C. § 102(b) and §103

The rejection of claims 26 to 56 under 35 U.S.C. § 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly obvious over Meyer, Accession number Q59306, is respectfully traversed.

As stated in the Office Action, Meyer describes a 190 amino acid sequence encoded within an EcoRI-Sau3A *Clostridium pasteurianum* fragment. The Office Action further indicates that Meyer reports the amino acid sequence HFKSK, which allegedly corresponds to five contiguous amino acids of SEQ ID NO:2. Although no nucleic acid sequence is reported in the cited reference, the Office Action indicates that all possible degenerate sequence variations resulting in expression of "HFKSK" are obvious in view of Meyer's reported amino acid sequence. The Office Action emphasizes that claims 29 to 41 and 44 to 56, which relate to nucleic acid molecules encoding at least 8 amino acids of SEQ ID NO:2, are only rejected because the specific amino acid residues recited by the respective claims allegedly are described by the reference, irrespective of sequence, since no "contiguous" or similar limitation has been set forth in the claims.

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 13

Regarding claims 26 and 28

Claims 26 and 28 are directed to an isolated nucleic acid molecule which includes a portion of SEQ ID NO:1 that encodes at least 5 contiguous amino acids of SEQ ID NO:2, or that encodes 5 to 50 contiguous amino acids of SEQ ID NO:2, respectively.

Applicants submit that the isolated nucleic acid molecules of claims 26 and 28 are novel over the cited reference. As discussed above, the claimed isolated nucleic acid molecules inherently include at least 15 nucleotides of SEQ ID NO:1. In contrast, the cited reference does not disclose any nucleic acid sequence, let alone the sequence of SEQ ID NO:1. Because Meyer, failing to describe SEQ ID NO:1, is not an enabling reference for each and every element of the claim, the cited reference cannot anticipate the claimed invention, which relies, in part, on SEQ ID NO:1.

In regard to the alleged obviousness of the claimed invention, the Office Action points to an amino acid sequence and the well known degeneracy of the genetic code. However, Applicants assert that the isolated nucleic acid molecules of claims 26 and 28 are unobvious over the cited reference in view of the genetic code. In particular, as upheld in the courts in *In re Bell* (991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993)) and *In re Deuel* (51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed Cir. 1995)), mere knowledge of the genetic code together with an amino acid sequence does not give rise to a *prima facie* case of

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 14

obviousness. No particular one of the many possible DNA sequences that encode the amino acid sequence "HFKSK" can be obvious unless there is something in the art to lead to the particular nucleic acid sequence of SEQ ID NO:1. In this case, there is no teaching other than the sequence "HFKSK" and, in particular, no teaching pointing to the specific nucleic acid sequence of SEQ ID NO: 1. Thus, the courts support that the isolated nucleic acid molecules are unobvious over the cited reference.

In view of the above remarks, Applicants respectfully request that the Examiner remove the rejection of claims 26 and 28 under 35 U.S.C. § 102(b) and, in the alternative, under 35 U.S.C. § 103.

Regarding claims 29 to 56

Each of claims 29 to 56 relate to nucleic acid molecules encoding at least 8 contiguous amino acids of SEQ ID NO:2. As acknowledged in the Office Action, Meyer at best reports the five residue sequence HFKSK, but does not describe at least 8 contiguous amino acids of SEQ ID NO:2. Absent the teaching or suggestion of such an amino acid sequence, the invention of claims 29 to 56 is novel and unobvious over Meyer. Accordingly, Applicants respectfully request that the Examiner remove the rejection of claims 29 to 56 under § 102(b) or, in the alternative, under 35 U.S.C. § 103.

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 15

Regarding new claim 57

New claim 57 is directed to an isolated nucleic acid molecule which includes a portion of SEQ ID NO:1 encoding between 6 and 100 contiguous amino acids of SEQ ID NO:2. As discussed above, Meyer at best reports a sequence of five amino acids (HFKSK) but does not teach or suggest a sequence of six or more amino acids of SEQ ID NO:2. Thus, the isolated nucleic acid molecule of claim 57 is patentable over Meyer.

CONCLUSION

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned agent or Cathryn Campbell.

Respectfully submitted,

January 9, 2003
Date

Andrea L. Gashler
Andrea L. Gashler
Registration No.: 41,029
Telephone No. (858) 535-9001
Facsimile No. (858) 535-8949

CAMPBELL & FLORES LLP
4370 La Jolla Village Drive
7th Floor
San Diego, California 92122
USPTO CUSTOMER NO. 23601

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 1

APPENDIX A

26. (Twice amended) An isolated nucleic acid molecule, comprising a portion of SEQ ID NO:1, said portion encoding at least [3] 5 contiguous amino acids of SEQ ID NO:2.

28. (Amended) The isolated nucleic acid molecule of claim 26 [27], encoding 5 to 50 contiguous amino acids of SEQ ID NO:2.

29. (Amended) The isolated nucleic acid molecule of claim 26, encoding at least 8 contiguous amino acids of SEQ ID NO:2.

30. (Amended) The isolated nucleic acid molecule of claim 29, encoding 8 to 50 contiguous amino acids of SEQ ID NO:2.

31. (Amended) The isolated nucleic acid molecule of claim 29, encoding 8 to 20 contiguous amino acids of SEQ ID NO:2.

32. (Amended) The isolated nucleic acid molecule of claim 26, encoding at least 10 contiguous amino acids of SEQ ID NO:2.

33. (Amended) The isolated nucleic acid molecule of claim 32, encoding 10 to 50 contiguous amino acids of SEQ ID NO:2.

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 2

34. (Amended) The isolated nucleic acid molecule of claim 32, encoding 10 to 20 contiguous amino acids of SEQ ID NO:2.

35. (Amended) The isolated nucleic acid molecule of claim 26, encoding at least 12 contiguous amino acids of SEQ ID NO:2.

36. (Amended) The isolated nucleic acid molecule of claim 35, encoding 12 to 20 contiguous amino acids of SEQ ID NO:2.

37. (Amended) The isolated nucleic acid molecule of claim 26, encoding at least 15 contiguous amino acids of SEQ ID NO:2.

38. (Amended) The isolated nucleic acid molecule of claim 37, encoding 15 to 20 contiguous amino acids of SEQ ID NO:2.

39. (Amended) The isolated nucleic acid molecule of claim 26, encoding at least 18 contiguous amino acids of SEQ ID NO:2.

40. (Amended) The isolated nucleic acid molecule of claim 26, encoding at least 20 contiguous amino acids of SEQ ID NO:2.

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 3

41. **(Amended)** The isolated nucleic acid molecule of claim 26, encoding at least 25 contiguous amino acids of SEQ ID NO:2.

42. **(Amended)** An isolated nucleic acid molecule, comprising a nucleic acid sequence encoding at least [5] 8 contiguous amino acids of SEQ ID NO:2.

45. **(Amended)** The isolated nucleic acid molecule of claim 42 [44], encoding 8 to 50 contiguous amino acids of SEQ ID NO:2.

46. **(Amended)** The isolated nucleic acid molecule of claim 42 [44], encoding 8 to 20 contiguous amino acids of SEQ ID NO:2.

47. **(Amended)** The isolated nucleic acid molecule of claim 42, encoding at least 10 contiguous amino acids of SEQ ID NO:2.

48. **(Amended)** The isolated nucleic acid molecule of claim 47, encoding 10 to 50 contiguous amino acids of SEQ ID NO:2.

49. **(Amended)** The isolated nucleic acid molecule of claim 47, encoding 10 to 20 contiguous amino acids of SEQ ID NO:2.

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 4

50. (Amended) The isolated nucleic acid molecule of claim 42, encoding at least 12 contiguous amino acids of SEQ ID NO:2.

51. (Amended) The isolated nucleic acid molecule of claim 50, encoding 12 to 20 contiguous amino acids of SEQ ID NO:2.

52. (Amended) The isolated nucleic acid molecule of claim 42, encoding at least 15 contiguous amino acids of SEQ ID NO:2.

53. (Amended) The isolated nucleic acid molecule of claim 52, encoding 15 to 20 contiguous amino acids of SEQ ID NO:2.

54. (Amended) The isolated nucleic acid molecule of claim 42, encoding at least 18 contiguous amino acids of SEQ ID NO:2.

55. (Amended) The isolated nucleic acid molecule of claim 42, encoding at least 20 contiguous amino acids of SEQ ID NO:2.

56. (Amended) The isolated nucleic acid molecule of claim 42, encoding at least 25 contiguous amino acids of SEQ ID NO:2.